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Aethlon Medical Announces FDA Approval Of IDE For Oncology Indications

Will allow initiation of Early Feasibility Study in Head and Neck Cancer

SAN DIEGO, Oct. 7, 2019 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a therapeutic medical device and technology company focused on unmet needs in global health, announced today that the FDA has approved its Investigational Device Exemption (IDE) application to initiate an Early Feasibility Study (EFS) of the Company's proprietary Hemopurifier® in patients with head and neck cancer in combination with standard of care pembrolizumab (Keytruda).

An EFS for a medical device is similar to a phase 1 study for a drug or biologic and as such this trial will enroll a small number of patients with advanced head and neck cancer who cannot be treated with surgery or radiation. In this patient population, pembrolizumab was recently approved for initial first line treatment. Non-clinical studies conducted by Aethlon Medical's collaborators and other investigators have suggested that a primary mechanism of resistance to pembrolizumab and other immuno-oncology drugs is the secretion by tumor cells of exosomes, which are small, sub-cellular particles that have previously been demonstrated to be cleared by the Hemopurifier. Based on this observation, in November 2018 the FDA granted the Hemopurifier® a Breakthrough Designation "…for the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease."

The primary endpoint for the EFS, which will enroll 10-12 subjects at a single center, will be safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. The IDE approval is subject to FDA approval of Informed Consent documents from the trial site. More details on the trial will be disclosed in the future.

"This IDE approval is a critical first step in our plans to develop the Hemopurifier for applications in oncology" stated Timothy Rodell, M.D., Aethlon's CEO. "We believe that the clearance of immunosuppressive tumor-derived exosomes has the potential to improve response rates to these already game-changing immuno-oncology agents. Our Breakthrough Designation has allowed us to move very quickly with rapid, frequent and helpful communication with the FDA and clearly demonstrates the value of the Breakthrough program."

About Aethlon Medical, Inc. and the Hemopurifier®

Aethlon Medical, Inc. is focused on addressing unmet needs in global health. The Aethlon Hemopurifier is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. In cancer, the Hemopurifier depletes the presence of circulating tumor-derived exosomes that promote immune suppression. These tumor derived exosomes also seed the spread of metastases and inhibit the benefit of leading cancer therapies. The Hemopurifier® is an FDA designated "Breakthrough Device" related to the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease cancer. The Hemopurifier also holds a Breakthrough Device designation related to life-threatening viruses that are not addressed with approved therapies.

Aethlon also owns 80% of Exosome Sciences, Inc., which is focused on the discovery of exosomal biomarkers to diagnose and monitor cancer and neurological disease progression. Additional information can be found online at www.AethlonMedical.com and www.ExosomeSciences.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve risks and uncertainties. Statements containing words such as "may," "believe," "anticipate," "expect," "intend," "plan," "project," "will," "projections," "estimate," "potentially" or similar expressions constitute forward-looking statements. Such forward-looking

statements are subject to significant risks and uncertainties and actual results may differ materially from the results anticipated in the forward-looking statements. Factors that may contribute to such differences include, without limitation, Aethlon Medical, Inc.'s (the Company) ability to successfully complete the Early Feasibility Study and future studies with its Hemopurifier and other potential products, the Company's ability to meet the minimum bid price and minimum stockholders' equity requirements of the Nasdaq Capital Market, or any other national securities exchange, its ability to raise additional funds and other risks. The foregoing list of risks and uncertainties is illustrative, but is not exhaustive. Additional factors that could cause results to differ materially from those anticipated in forward-looking statements can be found under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended March 31, 2019, and in the Company's other filings with the Securities and Exchange Commission, including its quarterly Reports on Form 10-Q. Except as may be required by law, the Company does not intend, nor does it undertake any duty, to update this information to reflect future events or circumstances.

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